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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,291	10/03/2005	Ju-Ock Nam	012679-113	6194

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EXAMINER	
BRADLEY, CHRISTINA	
ART UNIT	PAPER NUMBER
1654	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/552,291	NAM ET AL.	
	Examiner	Art Unit	
	Christina Marchetti Bradley	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 October 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/03/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Notice to Comply*.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of SEQ ID NO: 26 and cancer in the reply filed on 12/07/2006 is acknowledged.

Drawings

2. Figures 3d, 7a, 7b, 8a and 8b are objected to under 37 CFR 1.83(a) because they are illegible. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Sequence Compliance

3. This application is objected to because the amino acid sequences in figures 1, 4b, and 5 are not associated with sequence identifiers (SEQ ID NOs). All sequences longer than ten nucleotides or four amino acids referenced in the specification must include a SEQ ID NO and must be included in the Sequence Listing. See MPEP § 2421-2422. See Notice to Comply.

Claim Rejections - 35 USC § 112/101

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 11 and 12 provide for the use of peptides, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

6. Claims 11 and 12 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1, 2 and 7-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

9. Claims 1, 2 and 7-12 are drawn to peptides consisting of at least 18 amino acids and comprising the sequence YH or NH and at least three hydrophobic amino acids with bulky side chains. The specification discloses the complete structure of SEQ ID NOs: 11-26 and the partial structure of an additional subset of the broad genus. Specifically, the peptides of the invention may comprise sequences derived from the fas-1 domains of the βig-h3 protein: (I, D, E or K)-(E, A or Q)-L-(L, R or A)-(N, D or S)-(A, L, K or I)-(L or Y)-(R, N, L or K)-(Y or N)-H-(M, I or G)-(V, L, Q or G)-(G, K, T or D)-(R, S, L or E)-(R, A, E or I)-(V, M, T or L)-(L, C or V)-(T, A, G or S). The claimed genus is much broader than this well-defined subgenus. The minimal structural requirements for the genus are a sequence length of at least 18 and the incorporation of the motif YH or NH and three hydrophobic amino acids with a bulky side chain. An infinite number of peptide sequences could satisfy these minimal requirements. Despite this breadth, the specification does not disclose the complete or partial structure or chemical/physical properties of any peptides outside of the well-defined subgenus described above, or guidance on how to obtain specific peptides with the claimed ability to inhibit angiogenesis. Accordingly, in the absence of sufficient recitation of distinguishing

identifying characteristics, the specification does not provide adequate written description of the claimed genus.

10. *Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

11. With the exception of SEQ ID NOs: 11-26 and the sequences derived from the fas-1 domains of the βig-h3 protein, the skilled artisan cannot envision the detailed chemical structure of the peptide. Although the minimal structural requirements of the broad genus are defined, there are too many undefined structural features for the skilled artisan to know specifically which sequences possess the claimed functional characteristics. Therefore, conception is not achieved until reduction to practice has occurred. Adequate written description requires more than a mere statement that it is part of the invention. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016. One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

12. Therefore, only SEQ ID NOs: 11-26 and the sequences derived from the fas-1 domains of the βig-h3 protein, but not the full breadth of the claims, meet the written

description provision of 35 U.S.C. §112, first paragraph. In addition, claims 7, 8, 10 and 12 are drawn to methods and pharmaceutical compositions for the treatment and prevention of angiogenesis-related diseases. The specification fails to describe methods of treating and preventing angiogenesis-related diseases. Accordingly, the full breadth of claims 7, 8, 10 and 12 fails to meet the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

13. Claims 7, 8, 10 and 12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988) and are as follows:

The Nature of the Invention

14. The invention is drawn to methods and pharmaceutical compositions for the treatment and prevention of angiogenesis-related diseases.

The State of the Prior Art and its Predictability or Unpredictability

15. In examples 1-6 of the specification, Applicant summarizes the teachings of the prior art on the role angiogenesis plays in cancer, rheumatoid arthritis, psoriasis, diabetic eye disease, arterial sclerosis and inflammation and suggests that the antiangiogenic

compositions of the invention will be highly effective at preventing and treating these conditions. The specification does not cite any examples in the prior art of antiangiogenic compounds that have been successfully used to treat or prevent these diseases. Although it is well-established that angiogenesis occurs in each of these conditions, the effect of blocking angiogenesis on these conditions is not predictable. One can reason that inhibiting angiogenesis will limit the progression of diseases in which angiogenesis is involved, but this hypothesis is not substantiated by data in the specification. Although the use of some angiogenesis inhibitors to limit tumor growth has been reported (Weissbach *et al.*, WO 99/46282), there is no information in the prior art pertaining to the efficacy of the compounds of the instant application. See Genentech, Inc. v. Novo Nordisk, A/S, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention. Furthermore, there are no known treatments that can prevent cancer, rheumatoid arthritis, psoriasis, diabetic eye disease, arterial sclerosis and inflammation in all patients under all circumstances. Thus, there is a high level of unpredictability associated with these methods.

The Relative Skill of Those in the Art

16. The relative skill of those in the art is high.

The breadth of the claims

17. The claims are exceptionally broad with respect to both the compounds and their intended use. The minimal structural requirements for the compounds are a sequence length of at least 18 and the incorporation of either the motif YH or NH and three hydrophobic amino acids with a bulky side chain. An infinite number of peptide

sequences could satisfy these minimal requirements. The intended use of these compounds is likewise broad. Treatment and prevention of angiogenesis-related conditions encompasses the elimination and prevention of occurrence of all diseases related to angiogenesis in all patients, under all circumstances and for the entire life of the patient.

The Amount of Direction or Guidance Presented and the Presence of Working Examples

18. The specification fails to provide a single working example demonstrating that the claimed compounds can be used to treat or prevent an angiogenesis-related disease. The specification further fails to provide guidance on how to use the compounds in this manner or how to test the compounds for efficacy in treating and preventing the diseases.

19. The courts have stated that "tossing out the mere germ of an idea does not constitute enabling disclosure." Genentech, 108 F.3d at 1366 (quoting Brenner v. Manson, 383 U.S. 519, 536 (1966) (stating, in context of the utility requirement, that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion")). "[R]easonable detail must be provided in order to enable members of the public to understand and carry out the invention." Id. In the instant case, such reasonable detail is lacking. The specification provides no guidance on how to administer the compounds to patients with specific angiogenesis-related diseases or examples in which such administration resulted in treatment or prevention.

20. See Rasmusson v. SmithKline Beecham Corp., 75 USPQ2d 1297 (CA FC 2005) which teaches: "If mere plausibility were the test for enablement under section 112, applicants could obtain patent rights to "inventions" consisting of little more than respectable guesses as to the likelihood of their success. When one of the guesses later

proved true, the "inventor" would be rewarded the spoils instead of the party who demonstrated that the method actually worked. That scenario is not consistent with the statutory requirement that the inventor enable an invention rather than merely proposing an unproved hypothesis."

The Quantity of Experimentation Necessary

21. Considering the factors above, the skilled artisan would be burdened with undue experimentation in determining if one of the claimed peptides would be effective at treating or preventing an angiogenesis-related disease. The skilled artisan would be burdened with testing a broad range of peptides in *in vitro* angiogenesis assays. The active inhibitors would then have to be subjected to animal models of a broad range of diseases. The experimentation required represents years of inventive effort. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

Claim Rejections - 35 USC § 102

22. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

23. Claims 9 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Kim *et al.* (*J. Biol. Chem.*, **2002**, *277*, 46159-65, cited on Information disclosure statement filed 10/03/2005). Kim *et al.* teach a composition comprising SEQ ID NO: 26 that inhibits cell adhesion (see Figure 3 and page 46160, second column).

24. Kim *et al.* do not teach that the peptide can inhibit angiogenesis or cell migration or proliferation. Because the chemical structure of the species taught by Kim *et al.* is identical to the claimed invention, there is a reasonable expectation that the species would meet this additional functional limitation. The discovery and characterization of properties of a known material do not make it novel (see MPEP § 2112). Furthermore, there is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference (see MPEP § 2112).

25. If the composition is physically the same, it must have the same functional properties. "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990) See MPEP § 2112.01. Examiner cannot however determine whether or not the peptide taught by Kim *et al.* inherently possesses properties which anticipate or render obvious the claimed invention but has basis for shifting the burden of proof to applicant as in In re Fitzgerald, 619 F.2d 67, 205 USPQ 594 (CCPA 1980). See MPEP § 2112.

26. Claims 1, 2 and 7-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Weissbach *et al.* (WO 99/46282). Weissbach *et al.* teach a PRG-B polypeptide that is greater than 18 amino acids in length and contains the sequence YH and three hydrophobic amino acids with bulky side chains, III (see SEQ ID NO: 4 on page 3).

Weissbach *et al.* teach that the PRG-B polypeptide inhibits malignant tumors and angiogenesis in mice (examples 2 and 3, respectively).

Double Patenting

27. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

28. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

29. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

30. Claims 1-12 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1-6, 8-13 and 16 of copending Application No. 11/578,463. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-12 are generic to all that is recited in claim1-6, 8-13 and 16 of copending Application No. 11/578,463. That is claims 1-6, 8-13 and 16 of copending Application No. 11/578,463 fall entirely within the scope of claims 1-12 or, in other words, claims 1-12 are anticipated by claim1-6, 8-13 and 16 of copending Application No. 11/578,463. Specifically, claims 1-6, 8-13 and 16 recite methods for inhibiting adhesion, migration and/or proliferation of endothelial cells;

methods for inhibiting angiogenesis; methods for the treatment or prevention of angiogenesis-related disorders; and pharmaceutical compositions comprising a polypeptide comprising a fas-1 domain. Fas-1 domains have conserved YH or NH group and at least three bulky hydrophobic amino acids. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

31. No claims are allowed.

32. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christina Marchetti Bradley whose telephone number is (571) 272-9044. The examiner can normally be reached on Monday through Friday, 8:30 A.M. to 5:00 P.M.

33. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

34. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christina Marchetti Bradley, Ph.D.
Patent Examiner
Art Unit 1654

cmb

Cecilia J. Tsang
Supervisory Patent Examiner
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Notice to Comply	Application No. 10/552,291	Applicant(s) NAM et al.	
	Examiner Christina Marchetti Bradley	Art Unit 1654	

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e). The correct SEQ ID NO:2 is present in the paper copy of the of the sequence listing only. Therefore a search of the correct sequence is not possible.

☒ 7. Other: Drawings include amino acid sequences without SEQ ID NOs

Applicant Must Provide:

☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☒ An initial or substitute paper copy of the "Sequence Listing", **as well as an amendment specifically directing its entry into the application**.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216 or (703) 308-2923
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